K063021

NOV 2 2 2006

Safety and Effectiveness Summary for Profiler 2

Profiler 2 is only used by the radiation therapy professionals, and is not used with the patient. A standard commercial power converter converts the power from the wall outlet voltage (100 to 240 VAC) to 18 VDC. The converter is then connected to a power/data interface (PDI) and then supplies the 18 VDC power to the Profiler 2 through a single 8 pin DIN connector. A standard 9 pin serial connectors connects the PDI to a computer. The commercial power converter and PDI device are fully tested for safety. Therefore, Profiler 2 should not generate a shock hazard to the operator.

Sun Nuclear has deemed the devices safe and effective for their intended uses as long as they are used in accordance with all of the accompanying labeling and instructions. When used properly, Profiler2 can collect the useful dosimetry modeling data for radiation therapy treatment planning. Sun Nuclear believes that responsible design and quality assurance practices were followed during the development and manufacture of Profiler 2 (Model 1174).

Safety features of Profiler 2

Feature	Effect
1. Standard power converter	Eliminate electrical shock
2. Shielded housing	Prevent E&M interference
3. Line mark on device	Protect electronics being under direct radiation beam

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Noel M. Downey
Official Correspondent
Sun Nuclear Corporation
425-A Pineda Court
MELBOURNE FL 32940

NOV 2 2 2006

Re: K063021
Trade/Device Name: Profiler 2 Model 1174
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 29, 2006
Received: October 2, 2006

Dear Mr. Downey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K063021

Device Name: The Profiler 2

Indications for Use:

The Profiler 2 is a device that is designed for use as a radiation scanning system that is used to measure beam data in radiotherapy departments for dose modeling in the treatment planning computer.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use ✓ OR Over-The-Counter Use _____

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063021